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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,297	02/13/2002	Masako Yajima	219451US0	3488

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,297	YAJIMA ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT TO AMENDMENT, REMARKS, STATUS OF THE APPLICATION AND CLAIMS

1. The amendment to the specification and remarks filed 06/13/05 are acknowledged, entered and considered. Claims 9-32 are now pending in the application. The new matter objection to the specification and the rejection under 35 U.S.C. 103(a) over the prior art of record are withdrawn in view of Applicant's amendment and remarks filed 06/13/05. Applicant's remarks with respect to the rejection under 35 U.S.C. 103(a) over the prior art of record have been considered but deemed to be moot in view of the new ground of rejection. Also, the Finality of the previous Office action is withdrawn in view of the following new grounds of rejections as set forth *infra*.

NEW GROUND OF REJECTIONS

CLAIMS REJECTION-35 U.S.C. § 102(b)

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 15, 21 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Nitsche (U.S. Patent No. 5,240,909).

The reference of '909 patent discloses the administration of an effective amount of human lactoferrin (hLf) or animal lactoferrin as an active agent for suppressing inflammation caused by endotoxin LPS-derived from gram-negative bacteria, wherein the lactoferrin agent is administered orally or parenterally or enterally (See e.g., abstract, summary of the invention, cols. 10 and 12). Although, the reference does not disclose alleviating symptoms wherein the symptom is accumulation of body fluid containing albumin at the inflammation site (claim 9); accumulation of albumin at the inflammatory site (claim 15); decrease of albumin concentration in blood (claim 21); or increase of neutrophils in blood (claim 27). However, on col. 12, lines 61-65, the '909 patent clearly states that when lactoferrin was administered intravenously the initial increase in plasma endotoxin activity—one hour after administration of the antibiotic---was reduced by approx. 58.5% in comparison of the albumin control group. Thus, clearly showing the reduction of albumin concentration in blood, and as such meets the limitation of claim 21. Further, the above conditions/situations are natural occurrence due to the inflammation, and as such it is inherent property of lactoferrin administration to alleviate the symptoms of such condition/situation. Furthermore, as acknowledged by Applicant on page 2, paragraph 2 in the instant specification, it is known in the art that during sepsis caused by gram-negative bacilli, decline in blood albumin concentration, decrease of lymphocytic leukocytes, and increase of neutrophil occur. Also, on page 4, Applicant acknowledges that bovine-type lactoferrin has been used to demonstrate an effect of alleviating various symptoms, which appear after infection. Thus, albumin exudation or increase of blood neutrophils at the inflammatory site, these

are expected natural occurrence during inflammation whatever the cause of inflammation is. Moreover, in view of *In re Sussman*, 141 F. 2d 267, 60 U.S.P.Q. 538 (CCPA 1944), the claims are rejected under 35 U.S.C. 102(b) "that since the steps are the same, the results must inherently be the same unless they are due to conditions not recited in the claims." Applicant is claiming an invention employing the **same process steps** but the product(s) is (are) **alleged to be different**. Applicant is required to recite the missing steps to form the alleged different product(s) in view of the above citation. Thus, the prior art discloses the invention substantially as claimed, and as such, anticipates claims 9, 15, 21 and 27 as drafted.

CLAIMS REJECTION-35 U.S.C. § 103(a)

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-14, 16-20, 22-26 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitsche (U.S. Patent No. 5,240,909).

The reference of '909 patent teaches the administration of lactoferrin as an active agent for suppressing inflammation caused by endotoxin LPS-derived from gram-negative bacteria, wherein the lactoferrin is administered at a dosage of 0.1 mg/g and 300 mg/kg to inhibit endotoxins (See e.g., abstract and Example 4) and as such overlaps with the dosage ranges claimed in claims 10-14, 16-20, 22-26 and 28-32 (i.e., 0.1 to 1000 mg/kg). Thus, the reference clearly discloses the administration of lactoferrin as an active agent to suppress inflammation resulting in alleviating symptoms caused from LPS-induced inflammation due to acute inflammation or sepsis of the human by gram-negative bacteria. With respect to the dosage ranges and mode of administrations, the ranges and mode of administration disclosed by the reference and claimed by Applicant overlap in scope as discussed above, and as such, the selection of the appropriate dosages and route of administration would have been *prima facie* obvious because where general conditions of claims are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges or situations by routine experimentation. Further, Applicant's claims are directed to optimization of an "art recognized variable" which is within the purview of one of ordinary skill in the art, *In re Boesch*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

CONCLUSION AND FUTURE CORRESPONDANCE

4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

Mohamed/AAM
June 22, 2005